

REMARKS

Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 52-54 stand rejected under Section 103(a) as obvious over WO 96/08229 (“the ‘229 PCT application”) by itself or in view of U.S. Pat. No. 5,993,849 (“the ‘849 patent”). Applicants traverse this rejection on at least the grounds that it is based on a misunderstanding of “equivalence” and a misreading of the ‘229 PCT application.

Specifically, with respect to equivalence, the Examiner asserts that the equivalence of nicotine and fentanyl are taught in the art, specifically in the ‘849 patent, because fentanyl and nicotine form part of a Markush group in a single claim. (“The composition comprises acrylate copolymer and preferred drugs are exemplified by fentanyl and nicotine (claim 10). Therefore the art recognized the equivalency between nicotine and fentanyl in terms of drugs suitable for transdermal delivery from an acrylate copolymer composition.”) The M.P.E.P., however, states in Section 2144.06 that “the mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of those components.” Consequently, the Examiner’s obviousness rejection based on equivalence between nicotine and fentanyl, as established by their being claimed in a Markush group together cannot stand. For at least this reason, the obviousness rejection should be withdrawn.

With respect to the ‘229 PCT application interpretation, the Office has set forth a *prima facie* case of obviousness based on overlapping ranges. Specifically, the Office asserts that the ‘229 PCT application teaches that fentanyl can be used with the recited transdermal composition in an amount ranging from about 0.01 to 30 percent, which range encompasses that recited in the pending claims (about 8 to about 30%). Applicant respectfully submits that the Office’s contention is based on a misreading of the ‘229 PCT application, and that when properly read, the ‘229 PCT at best suggests that if fentanyl can be used with the disclosed transdermal delivery device, it would be used in amounts smaller than 8%. Specifically, the ‘229 PCT application indicates that for a given drug, a person of ordinary skill can readily determine the appropriate amount for inclusion in the transdermal delivery device. The ‘229 PCT application does not state at what amount each of the multitude of enumerated active ingredients would be included in the transdermal composition; rather the ‘229 PCT speculates that the amount would *generally*

fall *within* the range of from 0.01 to 30 percent—but not necessarily *encompass* the entire range of 0.01 to 30 percent for any or all of the active ingredients.

With respect to fentanyl, at the time the invention of the '229 PCT was made, a person of ordinary skill in the art would have understood (as evidenced by art submitted with previous response to office actions) that in fact the amount would not encompass the entire range, and would not be as high as 8%, because such a composition would not have been expected to be free of undissolved fentanyl. For example, in Roy et al., "Controlled Transdermal Delivery of Fentanyl: Characterizations of Pressure-Sensitive Adhesives for Matrix Patch Design," *J. Pharm. Sci.* 85(5):491 (1996), compositions containing over 4% fentanyl were observed to consist of both solution and dispersed fentanyl particles (see p. 494). Consequently, a person of ordinary skill would not have read the '229 PCT application as suggesting the use of fentanyl at percentages as high as 8% and therefore would not read the '229 PCT as disclosing, with respect to fentanyl, a range that overlaps the range recited in the pending claims. Thus the overlapping range basis for the *prima facie* obviousness rejection cannot stand.

Furthermore, as discussed above and in previous responses, because there was no reasonable expectation that a composition as claimed could comprise from about 8 to about 30% fentanyl, wherein the composition is free of undissolved fentanyl, a *prima facie* obviousness case cannot be asserted even when the '229 PCT application is properly read. For at least these reasons, the 103 rejection should be withdrawn.

In the event the Office continues to interpret that the '229 PCT application as suggesting the use of fentanyl over the entire range of from about 0.01 to 30 percent and therefore assert that a *prima facie* case of obviousness has been established, then Applicant respectfully asserts that it has rebutted the *prima facie* case with evidence of unexpected results. The M.P.E.P. at Section 2144.05(III) states that an applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing that there are new and unexpected results relative to the prior art. Applicant has shown just this in the art submitted with previous responses. Specifically, Applicant has shown that at the time the invention was made it was unexpected that a composition such as the one claimed could comprise fentanyl in a range as high as from about 8 to about 30%, wherein the composition is also free of undissolved fentanyl. Consequently, the 103 rejection should be withdrawn for this additional reason.

Please consider the application in view of the amended claims.

Respectfully submitted,

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Date

By: /Ted K Ringsred/

Ted K. Ringsred, Reg. No.: 35,658

Telephone No.: 651-736-5839

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833